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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HISSONG, BRUCE D	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/663,264	WARNE ET AL.	
	Examiner	Art Unit	
	Bruce D. Hissong, Ph.D.	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/27/2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-52* is/are pending in the application.

4a) Of the above claim(s) *42-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09/16/2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal matters

1. The Applicant's response to the requirement for restriction, mailed on 9/27/2005, was received on 10/27/2005, and has been entered into the record.

2. Claims 1-52 are currently pending. Claims 42-52 have been withdrawn as being drawn to a non-elected invention. Therefore, claims 1-41 are the subject of this office action.

Election/Restrictions

Applicant's election with traverse of Group II in the reply filed on 10/27/2005 is acknowledged. The traversal is on the ground(s) that there is no undue burden in searching the subject matter of Groups I and IV along with Group II. The subject matter of Group II is drawn to a pharmaceutical composition comprising an interleukin-11 (IL-11) polypeptide, while that of Group I is drawn to a pharmaceutical composition comprised of a bioactive polypeptide. The invention of group IV is drawn to a pharmaceutical composition comprised of IL-11, and further comprised of several coating layers. The Applicants argue that searching the subject matter of Group II would necessarily encompass the subject matter of Groups I and IV. Because IL-11 can be considered a bioactive peptide, and the subject matter in the claims of Group IV considerably overlaps with the claims of Group II, this argument has been found persuasive. Additionally, the subject matter of claim 27 is encompassed by the Group IV. Accordingly, claims 1-41 are the subject of this office action. Restriction between Groups III and V – VII is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

The information disclosure statements filed on 12/12/2003, 01/06/2004, and 03/01/2004 have been entered into the record, and have been fully considered by the Examiner. Reference C2 on the information disclosure statement filed on 03/01/2004 has been lined through because an international search report is not proper subject matter for an information disclosure statement. The reference on the report should be listed separately.

Drawings

The drawings are objected to because parts of the text overlap with other parts of the figure. In Figure 1, the phrase "copolymer (Eudragit L30D-55) enteric coat" overlaps with the drawing. In Figure 2, the phrase "DRUG LAYER" overlaps with the second text box.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The specification is objected to for the improper use of trademarks. The use of the trademarks EUDRAGIT, AVICEL, METHOCEL, SYLOID, and TWEEN 80 have been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks.

Claim Objections

1. Claim 9 is objected to for being self-referential. For the purpose of this Office Action, the Examiner has interpreted claim 9 as depending from claim 5.

2. Claims 10-12 and 16-18 are objected to for depending from an objected base claim.

3. The Examiner objects to the format of claims 1 and 5. The claims can be improved by amending to the claims to include numbering or lettering for each part of the claimed composition. As an example, the Examiner suggests claim 1 be amended to read:

".....wherein said composition comprises:
(a) a bioactive polypeptide, wherein said polypeptide.....
(b) at least one plasticizer....."

Claim Rejections - 35 USC § 112, first paragraph - enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-4, 13-15, and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a bioactive polypeptide that is IL-11, does not reasonably provide enablement for any other bioactive polypeptide. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The factors to be considered when determining if the disclosure satisfies the enablement requirement have been summarized as the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breath of claims. Ex Parte Forman, (230 USPQ 546 (Bd. Pat. App. & Int. 1986); In re Wands, 858 F.2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988).

The breadth of the claims is excessive because, as written, the claims read on any bioactive peptide having a basic pI, no more than one cysteine residue, and/or lacking an N-linked glycosylation site. Additionally, claim 4 is drawn to polypeptides with no cysteine amino acids. There are potentially numerous polypeptides, both naturally occurring and specifically engineered, that can meet these limitations. The specification does not teach the identity of any bioactive polypeptide, other than the recombinant human IL-11 of the Examples, that meets these limitations, and also provides no guidance or examples, other than rhIL-11, of

polypeptides with no cysteine amino acids. The specification asserts that the IL-11 polypeptide does not contain any cytsteine amino acids. However, human IL-11, as listed as NCBI ascession number AA013493, contains two cysteine amino acid residues. As discussed in the following section, the specification does not limit "an IL-11 polypeptide" to a specific polypeptide, and since a sequence of IL-11 is not provided in the form of a sequence listing, it is not clear if IL-11 polypeptide does or does not contain a cysteine residue(s). If IL-11 does indeed contain a cysteine residue, as suggested by the polypeptide of NCBI ascession number AA013493, then the specification is not enabled for any protein with no cysteine residues. There is no guidance in the specification, or working examples, that that teach which polypeptides, other than the recombinant human IL-11 of the Examples, can be used with the claimed invention, and a person of ordinary skill in the art would not be able to predict which bioactive polypeptides, other than rhIL-11, could be used in the invention set forth in the claims. It would require undue experimentation on the part of the skilled artisan to identify such bioactive polypeptides, and then to determine if they can be used in the claimed invention. Therefore, due to the excessive breath of the claims, the lack of guidance and working examples in the specification, the unpredictability of identifying and using any bioactive polypeptide that meets the limitations of the claims, and the amount of further experimentation necessary to identify such polypeptides, a person of ordinary skill in the art would only know how to use IL-11 in the present invention. Thus, the claims do not meet the 35 U.S.C. 112, first paragraph, requirement for enablement.

2. Claims 5-12, 16-26, and 28-41 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the recombinant human IL-11 of the Examples, does not reasonably provide enablement for all other IL-11 polypeptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are excessively broad because they read on "an interleukin-11 (IL-11) polypeptide". The specification does not specifically teach any specific IL-11 sequence (e.g. in a sequence listing). Furthermore, the working examples provided in the specification do not teach the specific identity of the IL-11 polypeptide used, other than to state it is recombinant human IL-11 (rhIL-11). Therefore, the claims can be interpreted as reading on any IL-11 polypeptide, from any species. This definition of IL-11 polypeptide can also encompass any full-length IL-11 polypeptide, as well as fragments of IL-11 polypeptides, as well as IL-11 mutated in

any way. The specification, on page 7, lines 25-27, states "IL-11 encompasses the protein produced by the sequences presently disclosed in the art, as well as proteins characterized by the modifications described above yet which retain substantially similar activity". Also, on page 6, lines 9-10, the specification asserts "any form of IL-11, which retains IL-11 activity, is useful according to the present invention." A cursory search of the NCBI protein database revealed many separate IL-11 polypeptide sequences. A person of ordinary skill in the art would not be able to predict which of the many IL-11 polypeptide sequences disclosed in the prior art could be used in the instant invention commensurate with it's intended use, namely administration to mammals to treat disease. For example, could IL-11 from fish, such as that of NCBI accession number CAI29480, be used in the instant invention and still possess the desired utility of treatment of mammalian disease? A trained artisan would require undue experimentation to determine if the many known IL-11 polypeptides could be used in the instant invention commensurate with the scope of the claims.

In addition, the claims broadly read on any IL-11 polypeptide that has been synthetically produced, or modified, for example, by deletion, substitution, addition of amino acids, polyethylene glycol, or glycosylation site (see p. 6, line 11 – p. 7, line 23). The language of the claims, as well as the specification, does not limit the nature, or number, of any potential modification to an IL-11 polypeptide, and therefore the claims are excessively broad. There is no guidance in the specification, or any working examples, for the use of any modified or synthetically produced IL-11 polypeptide. A person of ordinary skill in the art would not be able to predict which amino acid residues, or regions/domains of the polypeptide, could be modified in any way and still retain the desired function so as to allow its use in the claimed invention. Such determination of which amino acid residues could be modified, in any way, in any IL-11 polypeptide, would constitute undue experimentation on the part of the skilled artisan.

Therefore, due to the excessive breadth of the claims, which read on virtually any IL-11 polypeptide, the lack of guidance and working example in the specification, and the unpredictability of the art and the instant invention, and person of ordinary skill in the art would not know how to make and use the invention commensurate with the claims.

3. Claims 1-26 and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the use of talc as a glidant, does not reasonably provide enablement for the use of any other substance as a glidant. The specification does not enable

any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims read on a pharmaceutical composition containing a glidant, wherein at least one glidant is talc. The breadth of the claims is excessive, because any glidant can be used commensurate with the claims, as long as at least one glidant is talc. Neither the claims nor the specification limits the number of glidants that can be used. Although the specification teaches the use of talc as a glidant, there is no guidance or working examples of any other type of glidant that could be used in the composition of the instant invention. The effects any glidant(s), other than talc, would have on the chemical and physical properties of the claimed invention would be unpredictable to a person of ordinary skill in the art. It would require undue experimentation on the part of the skilled artisan to determine which glidants, other than talc, can be used in the claimed invention. Thus, due to the broad nature of the claims, the lack of guidance and working examples in the specification, the unpredictability of the invention and the art, and the amount of experimentation required of a skilled artisan to use any glidant other than talc, the claims do not meet the 35 U.S.C. 112 first paragraph requirement for enablement.

Claim Rejections - 35 USC § 112, first paragraph, written description.

Claims 1-41 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

1. Claims 1-4, 13-15, and 17 are drawn to a pharmaceutical composition comprising a bioactive polypeptide. The specification does not teach the identities of any bioactive polypeptides, other than IL-11. Additionally, the claims do not require that the bioactive polypeptides of the present invention possess any specific biological activity, nor any particular conserved structural or physical feature other than having a basic pI, no more than one cysteine residue, and lack an N-linked glycosylation site. Thus, the claims are drawn to a genus of polypeptides that are defined only by those characteristics.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the claimed

genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof. In this case, the only factors present are the requirements for basic pI, having no more than one cysteine residue, and lack of an N-linked glycosylation site. Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, the claimed bioactive polypeptides of claims 1-4 and 13-15 do not meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

2. Claims 5-12, 16-26, and 28-41 are drawn to a pharmaceutical composition comprised of IL-11 polypeptide. As previously described in part 2 of the 35 U.S.C. 112, first paragraph, enablement rejection, the claims read on any IL-11 polypeptide, naturally occurring or modified in any way, and from any species. The specification does not disclose any further distinguishing

characteristics, such as structural or sequence information, and only states that the polypeptide be an IL-11 polypeptide. The IL-11 polypeptides can therefore be any IL-11 polypeptide, which can include full-length IL-11, and fragments or mutants of IL-11. There is no description of any fragments, or mutated or modified IL-11 polypeptides, and no disclosure of any IL-11 other than the recombinant human IL-11 polypeptide of the working examples. Furthermore, there is no description of what critical residues must be maintained in order to retain the functional bioactivity of full-length IL-11. Thus, Applicants are claiming a genus of polypeptides, based only on functional similarity to rhIL-11, for which the specification provides no support. Therefore, for the reasons stated in the section above, the Applicants have not provided adequate written description for the claimed genus of IL-11 polypeptides.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention. The claims are drawn to a pharmaceutical composition comprising a *bioactive* polypeptide. The claims essentially read on any biologically active polypeptide. Therefore, the metes and bounds of the term "bioactive" are unclear, because different polypeptides can have widely different biological activities in many different cell types and physiological settings.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 1-22, 25, and 27-41 are rejected under 35 U.S.C. 103(a) as being unpatentable in view of Savastano *et al* (US patent 5,681,584). The claims of the instant application are drawn to a delayed-release, oral dosage pharmaceutical composition, comprising a bioactive polypeptide, and further comprising at least one binder, at least one plasticizer, at least one glidant, and a methacrylic acid copolymer. In some embodiments, the pharmaceutical composition is enveloped by a first sealing coat, an enteric coating layer, and a second sealing coat. Savastano *et al* describe a controlled release drug delivery device which consists of a core containing the bioactive therapeutic agent, and a first coating layer (called a "delay jacket"), an enteric coating layer (termed a "semi-permeable membrane"), and a second coating layer (referred to as the "enteric" layer in Savastano *et al*, but having the features of the claimed second coating layer of the instant application).

Specifically, Savastano *et al* teaches a core which can be comprised of active agents which can include proteins and polypeptides, including interferons and interleukins (column 6, lines 33-39). The core is further comprised of several pharmaceutical excipients, including carbohydrates and amino acids (column 7, lines 24-30). In particular, the inclusion of sucrose (column 7, line 42) and the amino acid methionine (column 7, line 44) are taught by Savastano *et al*. Additionally, Savastano *et al* also teaches the inclusion of the surfactant polysorbate 80 in the pharmaceutical composition (column 7, lines 64-65).

Savastano *et al* also teach the use of:

i. at least one binder, hydroxypropylmethylcellulose (HPMC – column 8, line 4)

ii. at least one plasticizer (polyethylene glycol or polypropylene glycol – column 7, lines 46-47, column 8, lines 14-17, and column 9, lines 31-32)

iii. at least one glidant (talc – column 7, line 54)

iv. a methacrylic acid copolymer (column 9, line 66 and column 10, lines 13-16), applied as a dispersion (column 10, lines 46-57).

Furthermore, Savastano et al teaches a biologically therapeutic agent in a core comprised of the excipients described above, and also surrounded by an inner coating layer, an enteric layer, and an outer coating layer. Although the terminology used is not identical to that of the instant application, the both the function and the composition of the layers is the same.

It would have been obvious to a person of ordinary skill in the art, at the time the instant application was filed, to follow the teaching of Savastano *et al* to practice the claimed invention of the instant application. Savastano *et al* is silent in regards to the inclusion of IL-11, or any bioactive polypeptide with a basic pI, or having one or no cytsteine residues, or lacking an N-linked glycosylation site. However, Savastano et al does disclose that the active agent can include polypeptides, such as interleukins. Because IL-11 is an interleukin, it would have been obvious to a trained artisan to incorportate IL-11 into the composition described by Savastano et al. Furthermore, Savastano et al teach that the active agent can be any protein or polypeptide, which a trained artisan would understand to encompass polypeptides with a basic pI, or lacking N-linked glycosylation site, or having one or less cytsteine residues.

Both Savastano *et al* and the instant application teach a pharmaceutical core surrounded by an inner layer, and both specify that the inner layer may be comprised of HPMC (column 8, lines 34-41 and column 9, lines 28-32). Savastano *et al* and the instant application also both teach a middle layer comprised of a methacrylic acid copolymer (column 9, line 66, and column 10, lines 13-16). Specifically, Savastano et al and the instant application both specify the use of the methylacrylic acid copolymer EUDRAGIT (column 10, lines 46-57). Finally, both Savastano et al and the instant application claim the use of an outer coating layer comprised of HPMC (column 11, line 36), and teach the formulation as an tablet (see Examples 1-4). Thus, Savastano *et al* specifically meets the limitations of claims 28-38.

Therefore, because Savastano et al teach a composition with an active agent that encompasses any protein or polypeptide, and specifically interleukins, and furthermore comprises the same excipients and structural features as the instant application, a person of ordinary skill in the art would have both the motivation, and a reasonable expectation of success, to follow the teachings of Savastano et al to practice the claimed invention commensurate with the scope of the claims.

The claims of the instant invention are drawn to the inclusion of several pharmaceutical excipients at various final percentages. As described above, Savastano *et al* teaches the use of a carbohydrate, amino acids such as methionine, methacylic acid copolymers, HPMC, and talc.

Savastano *et al* is silent in regards to the final percentage of each excipient in the final composition. However, optimization of excipients is common in the pharmacological arts. A person of ordinary skill in the art would have both the movitation, and the technical expertise, to optimize the excipients listed above, and would have a reasonable expectation of success in doing so and arriving at the concentrations of the instant invention.

The claims of the instant invention are drawn to a pharmaceutical composition, as described above, in capsule form. Although Savastano *et al* teaches a composition in tablet form and is silent in regards to a composition in capsule form, pharmaceuticals in capsule form are well-known in the art. It would require routine optimization for a skilled artisan to adapt the composition of the instant invention to capsule form, and the skilled artisan would have both the motivation, and the technical expertise to do so with a reasonable expectation of success.

2. Claims 23, 24, and 26 are rejected under 35 U.S.C 103(a) as being unpatentable over Savanstano *et al*, in view of Porter (In Remington's Pharmaceutical Sciences, 19th Ed., 1995, Chapter 93, p 1653, 1st column, 9th paragraph). The claims of the instant invention are drawn to a pharmaceutical composition, described above, which contains triethyl citrate as a plasticizer. The teachings of Savastano *et al* are described above. Savastano *et al* does not teach the use of triethyl citrate as a plasticizer. However, Porter does teach that plasticizers are often incorporated into pharmaceutical compositions, and lists triethyl citrate as an accepted plasticizer. Because of its accepted use in the art, a skilled artisan would be motivated to combine the teachings of Savastano *et al* with those of Porter to incorporate triethyl citrate into the composition of the instant invention, and would also have the technical expertise and experience to optimize the concentration.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225

USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1. Claims 1-5, 13-20, 28-31, and 38-39 are provisionally rejected on the ground of nonstatutory double patenting over claims 13, 15, 20, 22-23, 25, and 28 of copending Application No. 10/360906. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: The claims of the instant application, and of copending application 10/360906 are both drawn to a pharmaceutical composition comprised of IL-11 and various pharmaceutical exicipients, including methacrylic acid copolymers, and cellulose ethers. Furthermore, both applications teach the pharmaceutical composition in tablet form.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce D. Hissong, Ph.D. whose telephone number is (571) 272-3324. The examiner can normally be reached M-F from 8:30am - 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can

be reached at (571) 272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDH
Art Unit 1646

ROBERT S. LANDSMAN, PH.D
PRIMARY EXAMINER